

Remarks

Claims 12-23 and 27-36 are pending upon entry of the foregoing amendments.

Amendments to the Claims

Claims 1-11 were previously cancelled and claims 24-26 were previously withdrawn as being drawn to a nonelected species. Applicants respectfully submit that rejoinder of claims 24-26 may be appropriate once a common technical feature is determined to be patentable.

Claims 12 and 28 are amended to clarify that the de-esterified pectin has a degree of esterification ranging from 60% to 30% and a molecular weight greater than the molecular weight of a de-esterified pectin prepared by acid hydrolysis or alkali hydrolysis. Support for this amendment may be found throughout the specification, including at paragraphs [0033], [0037], [0057], [0058], and [0069] of the published application and as illustrated in the Examples (compare, for example, the molecular weight of the de-esterified pectins of Table 1 to the de-esterified pectins of Table 2). No new material is believed to be added by these amendments.

Rejection Under 35 U.S.C. § 112

Claims 12-23 and 27-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The rejection is respectfully traversed. Applicants respectfully submit that the rejection is moot when applied to the claims as amended. Accordingly, withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. §103

Claims 12-23 and 27-36 are rejected under 35 U.S.C. § 103(a) as being obvious over International Publication WO 99/37685 to Marr et al. (hereinafter "Marr") in view of

International Publication WO 98/58968 to Larsen et al. (hereinafter "Larsen"). The rejection is respectfully traversed.

The Claimed Invention

The presently claimed invention generally is directed to amidated pectins having a low degree of esterification. Applicants have discovered that it is desirable to first use biocatalytic (e.g., enzymatic) de-esterification to reduce the degree of esterification of the pectin to between 60% and 30% without the occurrence of any significant depolymerization or loss of molecular weight. (Declaration Under 37 C.F.R. § 1.132 by Jens Trudso at paragraph 3 (hereinafter "Declaration")). The de-esterified pectins are subsequently amidated to provide amidated pectins that have a surprisingly low tendency towards aggregation, a surprisingly high molecular weight, and a surprisingly low loss of intrinsic viscosity as compared to amidated pectins prepared from conventional de-esterified pectins. (*Id.*).

One Skilled in the Art Would Not Combine the Teachings of Marr and Larsen

The Examiner continues to rely on the combination of Marr and Larsen to read on the Applicants' claimed amidated de-esterified pectins; however, one skilled in the art would not combine the teachings of Marr and Larsen because the references, when considered in their entirety, teach away from making any such combination. (Declaration at paragraphs 4-6). "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." (M.P.E.P. §2141.02).

Marr teaches that it is necessary to reduce the molecular weight of bulk-extracted pectin to improve the solubility of the de-esterified pectins

Marr discloses methods for preparing pectins having both a low degree of esterification and a reduced molecular weight. (Declaration at paragraph 4). The "low molecular weight

pectins” have a molecular weight in the range of 20,000 to 50,000 Daltons and are described as having good solubility, heat stability, and rheological properties. (*Id.*) These “low molecular weight pectins” optionally may be combined with a “high molecular weight pectin” to provide a combination suitable for use in various applications. (*Id.*)

Larsen teaches that it is essential to prepare separate fractions of high-esterified pectin because de-esterified and/or amidated pectin prepared from bulk-extracted pectin has undesirable properties

Larsen teaches that bulk-extracted pectin produces products having a number of undesirable properties (e.g., haze in gels, enhanced viscosity, incomplete solubility, and syneresis). (Declaration at paragraph 5). Larsen teaches that it is possible to overcome these complications by extracting high-ester pectin fractions having improved properties and performance as compared to bulk-extracted pectin. (*Id.*) These pectin fractions optionally may be de-esterified and/or amidated to obtain de-esterified and amidated pectin fractions. (*Id.*)

One skilled in the art would not combine the teachings of Marr and Larsen when the references are considered in their entirety

The references, when considered in their entirety, teach away from the Examiner’s proposed combination. (Declaration at paragraph 6). While Marr is directed to bulk-extracted pectins, Larsen is directed to pectin fractions and expressly teaches that use of bulk-extracted pectins is undesirable. (*Id.*) One skilled in the art would not seemingly rely on Larsen’s disclosure of amidated pectins while simultaneously disregarding Larsen’s disclosure that teaches away from use of bulk-extracted pectins. (*Id.*) Instead, one skilled in the art would rely on Larsen’s teachings in their entirety to modify Marr by using only pectin fractions in lieu of bulk-extracted pectins.

The present situation is analogous to that of *Schenck v. Nortron Corp.*, 713 F.2d 782 (Fed. Cir. 1983). In *Schenck*, the claimed invention was directed to a vibratory testing machine having a supporting means which formed “a single integral and gaplessly continuous piece.” The prior art perceived a need for mechanisms to dampen resonance; however, the inventor eliminated the need for dampening via the one-piece gapless support structure. The court found that “[b]ecause that insight was contrary to the understandings and expectations of the art, the structure effectuating it would not have been obvious to those skilled in the art.” (*Id.* at 785).

Here, the prior art perceived a need to improve the performance of bulk-extracted pectins by either reducing both the degree of esterification and the molecular weight of the bulk-extracted pectins (as taught in Marr) or by using pectin fractions in lieu of bulk-extracted pectins (as taught in Larsen). Applicants, however, have eliminated the need for either of these solutions. The insight here, as in *Schenck*, was contrary to the understandings and expectations of the art, and therefore would not have been obvious to those skilled in the art.

The Combination of Marr and Larsen Does Not Teach Applicants’ Claimed Invention

Moreover, neither of these references remotely teaches or suggests amidated pectins having the claimed characteristics or methods for preparing the amidated pectins. For example, neither of the cited references remotely teaches or suggests the desirability of minimizing the loss of the molecular weight during the de-esterification of the pectin or the desirability of minimizing the loss of intrinsic viscosity during the amidation of the pectin. (Declaration at paragraph 8).

In particular, the cited references do not remotely teach or suggest the claimed ratio, R2, of the intrinsic viscosity of the de-esterified pectin to the intrinsic viscosity of the amidated pectin of claims 12-14; that the molecular weight of the de-esterified pectin is greater than the

molecular weight of a de-esterified pectin prepared using conventional acid or alkali hydrolysis as in claims 12 and 27; or the Mark-Houwink factor of claims 18-20. Although both the intrinsic viscosity and Mark-Houwink factor are influenced by the molecular weight of the pectin (Paragraphs [0087] and [0276]), the combination of characteristics set forth in the claimed invention is inherent or obvious from the teachings of the cited references.

Applicants respectfully submit that the Examiner has failed to establish that the teaching of Larsen and Marr would render the claimed compositions and methods obvious. On the contrary, if one skilled in the art were to combine Marr and Larsen, a more plausible combination of the references would provide a method for preparing the high-ester pectin fractions using the teachings of Larsen, both reducing the degree of esterification and molecular weight using the teachings of Marr, and amidating the low molecular weight de-esterified pectins to provide amidated de-esterified pectin fractions having a low degree of esterification and a low molecular weight. The resulting product would not be an amidated pectin having a low degree of esterification and a high molecular weight. (See Declaration at paragraphs 7-8).

Secondary Considerations Overcome the Alleged *Prima Facie* Case of Obviousness

Even if the Examiner had set forth a *prima facie* case of obviousness, Applicants' surprising and unexpected results are sufficient evidence of secondary considerations to establish the nonobviousness of Applicants' claimed invention. Applicants have discovered that by first de-esterifying the pectin using biocatalytic de-esterification and subsequently amidating the de-esterified pectin, the depolymerization and aggregation of the amidated pectins can be significantly reduced. (Declaration at paragraph 9). Conventional methods of de-esterification and amidation will not provide Applicants' claimed invention absent an understanding of the

importance of avoiding the reduction of molecular weight of the pectin during both the de-esterification and amidation steps and the concomitant effect of any reduction in molecular weight on the intrinsic viscosity and Mark-Houwink factor.

The surprisingly improved properties of the amidated pectins of the claimed invention are further set forth in the Examples of Applicants' specification and are summarized in the accompanying Declaration. In particular, Applicants have discovered that exemplary embodiments of the amidated pectins of the claimed invention have a surprisingly high molecular weight, a surprisingly low loss of intrinsic viscosity, and produce gels having surprisingly good rheological properties.

- Molecular Weight: Conventional acid de-esterification reduced the molecular weight of the de-esterified pectins by 34-49% while the biocatalytic de-esterification reduced the molecular weight of the de-esterified pectins by only 7-13%. (Declaration at paragraph 9a).
- Intrinsic Viscosity: Subsequent amidation of conventional acid de-esterified pectins resulted in a 15-54 % reduction in intrinsic viscosity while the subsequent amidation of biocatalytic de-esterified pectins resulted in a 3-18 % reduction in intrinsic viscosity. (Declaration at paragraph 9b).
- Gel Strength: Synthetic gels prepared with amidated pectins prepared using conventional acid de-esterification had significantly lower gel strength as compared to synthetic gels prepared with the amidated pectins of the claimed invention. (Declaration at paragraph 9c).

The Examiner appears to erroneously disregard Applicants' evidence of surprising and unexpected results, stating only that some of the properties overlap and thus do not appear to be significantly different.¹ Applicants respectfully disagree, and submit that there is a significant improvement in the properties of the claimed amidated pectins over the amidated pectins prepared using conventional acid de-esterification when the properties are considered in their entirety. (See Declaration at paragraph 10). For example, exemplary embodiments of the claimed amidated pectins produced a gel having both a gel strength and a critical stress over two times greater than amidated pectins prepared using conventional acid de-esterification. One skilled in the art would not expect for the amidated pectins of the claimed invention to impart such significant improvements by merely reducing the loss of molecular weight and intrinsic viscosity – particularly in light of the teachings of Marr and Larsen.

A *prima facie* case of obviousness has not been made because the preponderance of the evidence over the entire record does not support the rejection.

Upon consideration of the entire record – including the prior art as a whole, the knowledge of those of ordinary skill in the art, the Applicants' specification, and the arguments provided in response to the Examiner's rejections – the evidence is insufficient to establish a *prima facie* case of obviousness by a **preponderance of the evidence**. The M.P.E.P. provides that:

The ultimate determination of patentability is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary consideration. The legal standard of 'a preponderance of evidence' requires the evidence *to be more convincing* than the evidence which is offered in opposition to it. With regard to rejections under 35

¹ Although the Examiner is correct in noting that *one* property has some overlap (e.g., the decrease in intrinsic viscosity over the range from 15% to 18%), the Examiner disregards that there not one of the comparative amidated pectins provided both a reduction in the loss of intrinsic viscosity and the loss of molecular weight as set forth in Applicants' claims.

U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than not. (M.P.E.P. 2142 (emphasis added, internal citations omitted)).

In the present application, the record as a whole is sufficient to teach or suggest an amidated pectin prepared by first contacting a starting pectin material with a bio-catalyst capable of de-esterifying the starting pectin material to produce a de-esterified pectin having a degree of esterification ranging from 60% to 30% and a molecular weight greater than the molecular weight of a de-esterified pectin prepared by acid or alkali hydrolysis of the starting pectin material, and subsequently contacting the de-esterified pectin with ammonia to produce an amidated pectin, wherein the amidated pectin is characterized by having a ratio, R2, of intrinsic viscosity of the de-esterified pectin to the intrinsic viscosity of the amidated pectin ranging from 1.01 to 1.15.

Moreover, in weighing the Examiner's contentions about Marr and Larsen against the evidence of record, it is submitted that the opinion of the U.S. Court of Customs and Patent Appeals given in Application of Hummer, 44 C.C.P.A. 814, 819 (1957) is particularly fitting in the instant application. Judge Rich, in reversing an obviousness rejection, stated that:

'The mere fact that the elements of applicants' process may be found in various patents does not necessarily negative invention... . Moreover, the concept of doing a thing, the result of which is new and useful and unexpected, must be considered along with the actual steps of doing it in considering the presence or absence of invention and patentability.' The same principals are applicable to a mechanical combination. **We think any doubt on the question of patentability should be resolved in favor of the applicant.**

(*Id.* (emphasis added, internal citations omitted)).

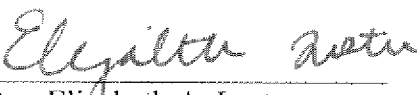
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AMENDMENT AND
RESPONSE TO OFFICE ACTION

In light of the foregoing facts and legal standards, Applicant respectfully submits that the combination of references fails to render obvious Applicant's claimed compositions and methods. The rejections therefore must be withdrawn.

Conclusion

For the foregoing reasons, Applicants respectfully submit that all claims are patentable. Allowance of all claims is respectfully requested. If there are any issues which can be resolved by telephone conference or an Examiner's Amendment, the Examiner is invited to contact the undersigned attorney at 404.853.8012 or elizabeth.lester@sutherland.com.

Respectfully submitted,


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